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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/609,206

06/26/2003

Daniel J. Potter

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SJM/AFD-WILEY

14901 DEVEAU PLACE

MINNETONKA, MN 55345-2126

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

03/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/609,206 | Applicant(s) POTTER ET AL. | |
| | Examiner DIANE YABUT | Art Unit 3734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/21/2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 45-46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBroom et al., hereinafter "**McBroom**" (U.S. Patent No. **6,277,108**).

Claims 45-46 and 48: McBroom discloses a sheath body **140**, the sheath body having a distal end and including a longitudinally extending sheath score line ("weakened portion") running along a length of the sheath body, and a tearable, contiguous radiopaque ring **160, 330, 500** or **700** abutting a distal end of said sheath body, the radiopaque ring defining gaps or score lines ("perforated lines") **512** running along the

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radiopaque ring and separating several marker segments which may be broken by tearing and may be aligned with said sheath score line (“as the sheath **140** is severed, the marker band **160** is also severed”). The radiopaque ring score line may be located or bonded to an inner wall of the sheath body. See abstract, Figures 1, 4, 6, 9; col. 1, lines 38-41, col. 3, line 54 to col. 4, line 67, and col. 5, lines 3-34.

McBroom does not expressly disclose first and second marker segments being discrete, or separate and not connected to one another. However, McBroom teaches several radiopaque marker segments including several gaps **512** in Figure 6 which may be separate the radiopaque marker into discrete segments by using slots, such as vertical slot **712**. It would occur to one of ordinary skill in the art to have two discrete marker segments in order to further facilitate splitting the combined sheath and radiopaque marker simultaneously, and therefore make them easily removable from a medical device (col. 6, lines 2-12). It is also noted that applicant has disclosed in paragraph 8 of the specification that the discrete portions of the radiopaque marker “may or may not be in direct contact with one another.” Therefore, modifying the radiopaque marker segments of McBroom to be discrete would have occurred to one skilled in the art since applicant has not disclosed that having the segments be discrete solves any stated problem or is for any particular purpose and it appears that the radiopaque marker would perform equally well with the segments being discrete.

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4. Claims 47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over **McBroom** (U.S. Patent No. **6,277,108**) in view of **Dehdashtian et al.** (U.S. Patent No. **5,968,068**).

Claims 47 and 50: McBroom discloses the claimed device except for the radiopaque marker being embedded within the sheath body, or the distal end of the sheath body being separated into an inner ring and an outer ring via a longitudinal cut around its perimeter with the radiopaque ring sealed between the inner and outer rings.

Dehdashtian et al. teach a radiopaque marker **32** being embedded within a sheath body **23**, or the distal end of the sheath body being separated into an inner ring and an outer ring via a longitudinal cut around its perimeter with the radiopaque ring sealed between the inner and outer rings (Figure 8). It would have been obvious to one of ordinary skill in the art at the time of invention to embed the radiopaque marker of McBroom in the sheath body, as taught by Dehdashtian et al., to provide a smooth, non-traumatic outer surface of the sheath while still allowing the marker to be readily and apparently visible (col. 26, lines 30-36).

5. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over **McBroom** (U.S. Patent No. **6,277,108**) in view of **Norlander et al.** (U.S. Patent No. **6,562,049**).

Claim 49: McBroom discloses the claimed device, except for a second sheath score line running substantially along said length of the exterior surface of said sheath body,

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located approximately opposite the first sheath score line, which would align with the second marker score line or notch.

Norlander et al. teach first and second sheath score lines **46** running substantially along a length of a sheath body **11** and located approximately opposite one another along an interior of said sheath body (Figures 6-8; col. 6, lines 50 to col. 7, line 14). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a second sheath score line, as taught by Norlander et al., to McBroom since it was known in the art that multiple score lines facilitate removal of the sheath in that it can be split more efficiently when positioned at different orientations or when one score line is not easily accessible on the opposite side. Since McBroom anticipates multiple radiopaque marker score lines **512** it would occur to one of ordinary skill to align multiple sheath score lines to these to further facilitate splitting.

6. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over **McBroom** (U.S. Patent No. **6,277,108**) in view of **Norlander et al.** (U.S. Patent No. **6,562,049**) and **Dorn et al.** (U.S. Pub. No. **2002/0183826**).

Claim 51: McBroom and Norlander et al. disclose the claimed device (see paragraphs above) except for the inner surface of the tubular body of the radiopaque marker ring being formed in a funnel shape at a proximal end thereof.

Dorn et al. teach an the inner surface of a tubular body of a radiopaque marker **226** ring being formed in a funnel shape at a proximal end thereof (Figure 89). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a

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funnel shape to the radiopaque marker of McBroom, as taught by Dorn et al., in order to conform to a tapered tip of the sheath or to facilitate insertion into the body.

Response to Arguments

7. Applicant's arguments with respect to claims 45-51 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734